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510(k) Summary

Prepared : April 19, 1996

Trade Name: Monotube® Tube to Ring Clamp
Common Name: External Fixation Clamp
Classification Name: SMOOTH OR THREADED METALLIC BONE
FIXATION FASTENER 888.3040

This submission describes an external fixation clamp to used to provide a hybrid construct combining the pin fixation of the Monotube® External Fixation System with the Ring and wire fixation of the Monticelli/Spinelli Circular External Fixation System. This device is intended to provide stabilization of open and/or unstable fractures and where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting.

The Monotube® Tube to Ring Clamp is designed to connect the Ring of a Monticelli/Spinelli Circular Frame to a Monotube® Tube. The Clamp provides for angulation between the circular frame and the tube of the external frame system. The Clamp is manufactured from Stainless Steel and Aluminum.

Equivalency of this device is based on similarities in intended use, materials, design and operational principles to the Howmedica Monticelli/Spinelli Sliding Clamp (with Articulating Coupling), the Synthes Ring-to-Rod Clamp and the Zimmer Torus Ring-to-Rod Clamp.

Testing of this device is presented within the submission. Testing was preformed to compare the performance of the Monotube® Hybrid Frame versus a Monticelli/Spinelli Hybrid Frame using components of the Hoffmann External Fixation System.

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